DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

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COPY

November 2, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-13

Janet Fisher, President
Fisher Foods, Inc.
4402 Auburn Way North
Auburn, Washington 98002

WARNING LETTER

Dear Mrs. Fisher:

On September 1, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility at 4402 Auburn Way North, Auburn, Washington. At the conclusion of the inspection, Lester W. Fisher, Vice President, was presented with a Form FDA 483 listing serious deviations from Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the tuna salad sandwiches processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 123.

1. Your firm did not have a HACCP plan for your tuna salad sandwiches in a wedge shaped semi-rigid plastic container wrapped in plastic.

   21 CFR 123.6(b) requires seafood manufacturers to have and implement a HACCP plan when a hazard analysis has revealed one or more food safety hazards that are reasonably likely to occur. For your process, our investigator determined that pathogen growth and the presence of allergens are two hazards that are reasonably likely to occur and are not being controlled during storage of your tuna mixture and finished tuna sandwiches.

2. Your firm was not maintaining sanitation monitoring records for the eight areas of sanitation.

   21 CFR 123.11(b) and (c) require you to monitor all eight areas of sanitation and to maintain records of that monitoring and any corrections made as a result of monitoring.

During the previous inspection, on November 17, 1998, and in a letter from the FDA dated April 26, 1999, you were notified of the same deficiencies described in this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in ten months time your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

for Austin R. Long Ph.D.
Acting District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA